

104TH CONGRESS
2D SESSION

H. R. 3672

To amend the Federal Food, Drug, and Cosmetic Act to repeal the provisions for the certification of drugs containing insulin and antibiotics.

IN THE HOUSE OF REPRESENTATIVES

JUNE 18, 1996

Mr. WAXMAN introduced the following bill; which was referred to the Committee on Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to repeal the provisions for the certification of drugs containing insulin and antibiotics.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. REPEAL OF CERTIFICATION OF DRUGS CON-**
4 **TAINING INSULIN.**

5 Section 506 of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C 356) is repealed.

7 **SEC. 2. REPEAL OF CERTIFICATION OF ANTIBIOTICS.**

8 Section 507 of the Federal Food, Drug, and Cosmetic
9 Act (21 U.S.C. 357) is repealed.

1 **SEC. 3. CONFORMING AMENDMENT.**

2 Section 505 (21 U.S.C. 355) is amended by adding
3 at the end the following:

4 “(n)(1) On and after the date of the enactment of
5 this subsection, antibiotic drugs shall be considered new
6 drugs subject to this section. Except as provided in para-
7 graph (2), an antibiotic drug certified pursuant to section
8 507 before such date of enactment or exempted from cer-
9 tification pursuant to such section before such date of en-
10 actment shall be considered a new drug for which an appli-
11 cation has been filed pursuant to subsection (b) and ap-
12 proved for safety and effectiveness pursuant to subsection
13 (c) or, in the case of an abbreviated application under sec-
14 tion 507, shall be considered a new drug for which an ap-
15 plication has been filed and approved pursuant to sub-
16 section (j).

17 “(2) Subsection (c)(3)(D) or (j)(4)(D) shall not apply
18 to an antibiotic drug certified or exempted from certifi-
19 cation pursuant to section 507 before the date of the en-
20 actment of this subsection. Subsection (c)(3)(D) or
21 (j)(4)(D) shall apply to such antibiotic drug if, subsequent
22 to the date of the enactment of this subsection, the condi-
23 tions of approval of such drug are changed.”.

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